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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,888	09/15/2003	Robert E. Fischell	C1-03	1796

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EXAMINER	
RYCKMAN, MELISSA K	
ART UNIT	PAPER NUMBER
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,888	FISCHELL ET AL.	
	Examiner	Art Unit	
	Melissa Ryckman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn to a system for the percutaneous treatment of an aneurysm, classified in class 623, subclass 1.11.

II. Claims 24-26, drawn to a method for the percutaneous treatment of an aneurysm, classified in class 623, subclass 1.11.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device can be used for vaso-occlusion of an artery.

During a telephone conversation with Robert Fischell on 12/21/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11-20, 22, 23 rejected under 35 U.S.C. 102(b) as being anticipated by Greene, Jr. et al. (U.S. Patent No. 6,602,261).

Claim 1:

Greene, Jr. teaches a stent (60) with its sidewall covering the ostium of an aneurysm pocket that is formed in the wall of the artery of the human subject, the tent having a maximum circular opening diameter "L" between those stent struts that cover the ostium of the aneurysm pocket (Fig. 13), and a fill structure delivery system (40') for placing aneurysm pocket filling structures into the aneurysm pocket (42), the fill structure delivery system including a fill structure delivery catheter (40') that has a distal portion that is designed to be placed through the sidewall of the stent and into the aneurysm pocket (Fig. 13), the aneurysm pocket filling structures having a compressed minimum dimension "d" (col. 8 ll. 27,28), the filling expands to a minimum dimension "D" (col. 8, ll, 29) after deployed into the aneurysm pocket, the dimension "D" being sufficiently larger than the diameter "L" so the struts formed from the sidewall of the stent prevent the aneurysm pocket filling structures from passing out of the aneurysm pocket and into the arterial circulation (col. 15, ll. 67-col. 16, ll. 1,2).

Claims 8, 11-19:

Greene teaches a filling structure that is at least 3 mm when expanded (col. 8, ll. 29,36,37). Said filling structures are formed from an elastomer (col. 7, ll. 66) polyvinyl alcohol (col. 8, ll. 8) with a low hardness (col. 8, ll. 8,16) that a radiopaque material (col. 8, ll. 54) such as barium sulfate (col. 8, ll.54) has been added, said filling structures are filled with saline solution (col. 8, ll. 40). Said filling structures are coated with a material that improves their lubricity (col. 7, ll. 67, gel). Said filling structure is formed from an open cell elastomer (col. 8, ll. 22, foam).

Claim 20:

Greene teaches a fill structure storage tube that is part of the fill structure delivery system the fill structure delivery tube is designed to compress said filling structure (col. 8, ll. 30-35, Fig. 6).

Claim 22:

Greene teaches a pusher rod that pushes the aneurysm pocket filling into the aneurysm pocket (30, col. 14, ll. 16-20).

Claim 23:

Greene teaches an expandable filter that is designed to be placed into the artery of the human subject at a position that is distal to the ostium of the aneurysm pocket. Said fill structure (12) can also be used as filters.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene, Jr. et al. (U.S. Patent No. 6,602,261) as applied to claim 1 above, and further in view of Wang (U.S. Patent No. 6,652,575).

Greene, Jr. teaches the claimed invention but is silent regarding the material and coating of the stent, however Wang teaches a stent that elutes Taxol (col. 5, ll. 61) which decreases thrombotic activity, said stent is coated with heparin (col. 6, ll. 16). Said stent is made of stainless steel (col. 3, ll. 61). Said stent has a generally decreased cell size at its midsection compared to the size of the stent's cells near the ends of the stent (Fig. 12).

Wang does not specify that Taxol is used to decrease the incidence of subacute thrombosis, however this has been shown in the art to be successful in decreasing the incidence of subacute thrombosis.

It would have been obvious to one of ordinary skill in the art to use the stent of Wang with the filling structure of Green, Jr. because the stent is used to support the aneurysm pocket and provide a way of trapping the filling material into the aneurysm pocket.

Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene, Jr. et al. (U.S. Patent No. 6,602,261) as applied to claim 1 above.

Greene, Jr. teaches the claimed invention but does not specify the thickness of the wall of the fill structure, it would have been obvious to one of ordinary skill in the art to have a wall thickness of 0.001 and 0.020 inches as these dimensions are proportional to the diameter of the fill structures.

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene, Jr. et al. (U.S. Patent No. 6,602,261) as applied to claim 9 above, and further in view of Jacobsen (U.S. Patent No. 6,936,055).

Greene, Jr. teaches a hole through the fill structures (Fig. 3) but does not have a spherical fill structure, however Jacobson has a spherical fill structure (Jacobson, Fig. 1).

It would have been obvious to one of ordinary skill in the art to use the spherical structure of Jacobson with the fill structure of Greene because the fill structures expands radially.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene, Jr. et al. (U.S. Patent No. 6,602,261) as applied to claim 1 above, and further in view of Ken et al. (U.S. Patent No. 6,936,055).

Greene, Jr. teaches the claimed invention except for an extending shoulder on the catheter, however Ken teaches a catheter with an extending shoulder (Fig. 3B, 146).

It would have been obvious to one of ordinary skill in the art to have the catheter of Ken with the filling structure of Greene, Jr. because the catheter would be stopped from entering into to far into the aneurysm thus causing tissue damage.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(U.S. Patent No. 6.024,754) Engleson teaches an aneurysm closure method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

MJ Hayes

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER